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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Gleave, et al.

Application No.: 10/646,391

Filed: 8/21/2003

Title: Treatment of Melanoma by Reduction

in Clusterin Levels

Attorney Docket No.: UBC.P-035

Examiner:

Group Art Unit: 1614

Assistant Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants request that the references listed on Substitute for form PTO 1449, which is attached, be made of record in the US Patent and Trademark Office in the file relating to the above-captioned application. Copies of the listed references are enclosed.

Applicants enclose the fee for submission of this IDS. The Commissioner is authorized to charge any fees due in connection with this paper or credit any overpayment to Deposit Account No. 15-0610.

Cert. Under 37 CFR 1.8

This paper and the attachments named herein are being deposited with the United States Postal Service with sufficient postage as first class mail and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on

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Name Sandra Lahmann

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Respectfully Submitted,

Marina T. Larson, Ph.D

Attorney/Agent for Applicant(s)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE duction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known **Application Number** 10/646,391 INFORMATION DISCLOSURE Filing Date 8/21/2003 STATEMENT BY APPLICANT First Named Inventor Gleave et al. Art Unit (Use as many sheets as necessary) 1614

Examiner Name Sheet 1 Attorney Docket Number UBC.P-035

	,		U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where
	Nò.¹	Number-Kind Code ^{2 (il Innown)}	WIND-DD-1111	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-5,646,042	07-08-1997	Stinchcomb et al.	
•		US-5,789,389	08-04-1998	Tarasewicz et al.	
•		US-5,929,040	07-27-1999	Werther et al.	
		US-5,998,148	12-07-1999	Bennet et al.	
		US-6,172,216 B1	01-09-2001	Bennett et al.	
		US-6,335,194 B1	01-01-2002	Bennett et al.	
	ļ	US-6,383,808 B1	05-07-2002	Monia et al.	,
		US-2003/0158130 A1	08-21-2003	Gleave et al.	, :
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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ¢			
	· .	WO 00/34469	06-15-2000	The Research Foundation of					
		WO 00/49937	08-31-2000	The University of British					
		WO 01/46455 A2	06-28-2001	Yale University					
		WO 02/22635 A1	03-21-2002	ISIS Pharmaceuticals, Inc.					
·· ···································		WO 03/062421 A1	07-31-2003	The University of British					
1		WO 03/072591 A1	09-04-2003	The University of British					
		WO 2004/018675 A1	03-04-2004	The University of British					
		WO 2004/018676 A2	03-04-2004	The University of British					
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STATEMENT BY APPLICANT	First Named Inventor	Gleave et al.
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Sheet 2 of 4	Attorney Docket Number	UBC.P-035

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AGRAWAL ET AL., Antisense Therapeutics: is it as simple as complementary base recognition, Molecular Medicine Today, 2000, Page(s) 72-81, Volume 6, Publisher: Elsevier Science Ltd.	
		AOKI ET AL., RNA Intereference may be more potent than antisense RNA in human cancer cell lines, Clinical and Experimental Pharmacology and Physiology, 2003, Page(s) 96-102	
		BENNER ET AL., Combination of Antisense Oligonucleotide and Low-Dose Chemotherapy in Hematological Malignancies, Journal of Pharmacological and Toxicological Methods, 1997, Page(s) 229-235, Publisher: Elsevier Science Inc.	
		BORAL ET AL., Clinical evaluation of biologically targeted drugs: obstacles and opportunities, Cancer Chemother Pharmacol, 1998, Page(s) S3-S21, Publisher: Springer-Verlag	
		ANDREA D. BRANCH, A good antisense molecule is hard to find, TIBS, 1998, Page(s) 45-50, Publisher: Elsevier Science Ltd.	
		STEVEN BREM, MD, Angiogenesis and Cancer Control: From Concept to Therapeutic Trial, Cancer Control Journal, 1999, Volume 6, Number 5, Publisher: H. Lee Moffitt Cancer Center & Research Institute	
		BRUCHOVSKY ET AL., Control of Tumor Progression by Maintenance of Apoptosis, www.prostatepointers.org, 1996, Publisher: Wiley-Liss, Inc.	
		BUTTYAN ET AL., Induction of the TRPM-2 Gene in Cells Undergoing Programmed Death, Molecular and Cellular Biology, 1989, Page(s) 3473-3481, Volume 9, Number 8, Publisher: American Society for Microbiology	
		COX ET AL., Angiogenesis and non-small cell lung cancer, Lung Cancer, 2000, Page(s) 81-100, Publisher: Elsevier	
·		CROOKE ET AL., Basic principles of antisense therapeutics, Antisense Research and Application, 2004, Page(s) 1-50, Chapter 1, Publisher: Springer	
		DARBY ET AL., Vascular Expression of Clusterin in Experimental Cyclosporine Nephrotoxicity, Exp Nephrol, 1995, Page(s) 234-239, Publisher: S. Karger AG	

Examiner	Date	
Signature	Considered	1

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.•		DIEMER ET AL., Expression of Porcine Complement Cytolysis Inhibitor mRNA in Cultured Aortic Smooth Muscle Cells, The Journal of Biological Chemistry, March 15, 1992, Page(s) 5257-5264, Volume 207, Number 8, Publisher: The AMerican Society for Biochemistry and Molecular Biology, Inc.	
		GENTA, New Data Reaffirm Genta's Molecular Target as Critical Factor for Enhancing Anticancer Treatment, www.genta.com, 2001	
		JEN ET AL., Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies, Stem Cells 2000, 2000, Page(s) 307-319, Volume 18	
		KADOMATSU ET AL., Expression of sulfated glycoprotein 2 is associated with carcinogenesis induced by N-nitroso-N-methylurea in rat prostate, Cancer Res, April 1, 1993, Page(s) 1480-1483, Volume 53, Number 7	
		KIRBY ET AL, Bartonella-associated endothelial proliferation depends on inhibition of apoptosis, PNAS, April 2, 2002, Page(s) 4656-4661, Volume 99, Number 7	
×		KYPRIANOU ET AL., bcl-2 over-expression delays radiation-induced apoptosis without affecting the clonogenic survival of human prostate, International Journal of Cancer, January 27, 1997, Page(s) 341-348, Volume 70, Number 3	
	·	LEE ET AL., In Vitro Models of Prostate Apoptosis: Clusterin as an Antiapoptotic Mediator, The Prostate Supplement, 2000, Page(s) 21-24, Volume 9, Publisher: Wiley-Liss, Inc.	
		MILLAR ET AL., Localization of mRNAs by in-situ hybridization to the residual body at stages IX-X of the cycle of the rat seminiferous, International Journal of Andrology, 1994, Page(s) 149-160, Volume 17	
		MILLIS ET AL., Clusterin Regulates Vascular Smooth Muscle Cell Nodule Formation and Migration, Journal of Cellular Physiology, 2001, Page(s) 210-219, Volume 186, Publisher: Wiley-Liss, Inc.	
		MILNER ET AL., Selecting effective antisense reagents on combinatorial oligonucleotide arrays, Nature Biotechnology, 1997, Page(s) 537-541, Volume 15	
		NÖR ET AL., Engineering and Characterization of Functional Human Microvessels in Immunodeficient Mice, Laboratory Investigation, 2001, Page(s) 453-463, Volume 81, Number 4	

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Signature	Considered	

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		NÖR ET AL., Up-Regulation of Bcl-2 in Microvascular Endothelial Cells Enhances Intratumoral Angiogenesis and Accelerates Tumor Growth, March 1, 2001, Page(s) 2183-2188, Volume 61	
`		OPALINSKA ET AL., Nucleic-acid therapeutics: Basic principles and recent applications, Nature Reviews, 2002, Page(s) 503-514, Volume 1	-
1		TRAN ET AL., A role for survivin in chemoresistance of endothelial cells mediated by VEGF, PNAS, April 2, 2002, Page(s) 4349-4354, Volume 99, Number 7	
		TROUGAKOS ET AL., Silencing Expression of the Clusterin/Apolipoprotein J Gene in Human Cancer Cells Using Small Interfering RNA Induces, Cancer Research, March 1, 2004, Page(s) 1834-1842, Volume 64	
1		VICKERS ET AL., Efficient Reduction of Target RNAs by Small Interfering RNA and RNase H-dependent Antisense Agents, The Journal of Biological Chemistry, February 28, 2003, Page(s) 7103-7118, Volume 278, Number 9	
		WRIGHT ET AL., A ribonucleotide reductase inhibitor, MDL 101,731, induces apoptosis and elevates TRPM-2 mRNA levels in human prostate, Experimental Cell Research, January 10, 1996, Page(s) 54-60, Volume 222, Number 1	
		YANG ET AL., Nuclear clusterin/XIP8, an x-ray-induced Ku70-binding protein that signals cell death, PNAS, May 23, 2000, Page(s) 5907-5912, Volume 97, Number 11	
		ZWAIN ET AL., Clusterin Protects Granulosa Cells from Apoptotic Cell Death during Follicular Atresia, Experimental Cell Research, 2000, Page(s) 101-110, Volume 257, Publisher: Academic Press	
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